§ 600.90 Waivers.

(a) A licensed manufacturer may ask the Food and Drug Administration to waive under this section any requirement that applies to the licensed manufacturer under §§ 600.80 and 600.81. A waiver request under this section is required to be submitted with supporting documentation. The waiver request is required to contain one of the following:

(1) An explanation why the licensed manufacturer's compliance with the requirement is unnecessary or cannot be achieved,

(2) A description of an alternative submission that satisfies the purpose of the requirement, or

(3) Other information justifying a waiver.

(b) FDA may grant a waiver if it finds one of the following:

(1) The licensed manufacturer's compliance with the requirement is unnecessary or cannot be achieved,

(2) The licensed manufacturer's alternative submission satisfies the requirement, or

(3) The licensed manufacturer's submission otherwise justifies a waiver.

PART 601—LICENSING

Subpart A—General Provisions

Sec.

Subpart B—Establishment Licensing

Subpart C—Product Licensing

Subpart D—Licensing of Foreign Establishments and Products

Subpart E—Accelerated Approval of Biological Products for Serious or Life-Threatening Illnesses

Subpart F—Confidentiality of Information

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263; 15 U.S.C. 1451–1561.

SOURCE: 38 FR 32052, Nov. 20, 1973, unless otherwise noted.

CROSS REFERENCES: For U.S. Customs Service regulations relating to viruses, serums, and toxins, see 19 CFR 12.21–12.23. For U.S. Postal Service regulations relating to the admissibility to the United States mails see parts 124 and 125 of the Domestic Mail Manual, that is incorporated by reference in 39 CFR part 111.

Subpart A—General Provisions

§ 601.1 Two forms of licenses.

There shall be two forms of licenses: establishment and product.

§ 601.2 Applications for establishment and product licenses; procedures for filing.

(a) *General.* To obtain a license for any establishment or product, the manufacturer shall make application

to the Director, Center for Biologics Evaluation and Research, on forms prescribed for such purposes, and in the case of an application for a product license, shall submit data derived from nonclinical laboratory and clinical studies which demonstrate that the manufactured product meets prescribed standards of safety, purity, and potency; with respect to each nonclinical laboratory study, either a statement that the study was conducted in compliance with the requirements set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance; statements regarding each clinical investigation involving human subjects contained in the application, that it either was conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter or was not subject to such requirements in accordance with § 56.104 or § 56.105, and was conducted in compliance with requirements for informed consent set forth in part 50 of this chapter; a full description of manufacturing methods; data establishing stability of the product through the dating period; sample(s) representative of the product to be sold, bartered, or exchanged or offered, sent, carried or brought for sale, barter, or exchange; summaries of results of tests performed on the lot(s) represented by the submitted sample(s); and specimens of the labels, enclosures, and containers proposed to be used for the product. The applicant shall also include a financial certification or disclosure statement(s) or both for clinical investigators as required by part 54 of this chapter. An application for license shall not be considered as filed until all pertinent information and data have been received from the manufacturer by the Center for Biologics Evaluation and Research. The applicant shall also include either a claim for categorical exclusion under § 25.30 or 25.31 of this chapter or an environmental assessment under § 25.40 of this chapter. In lieu of the procedures described in this paragraph, applications for radioactive biological products shall be handled as set forth in paragraph (b) of this section. The applicant, or the applicant's attorney, agent, or other authorized official shall sign the application. In lieu of the procedures described in this paragraph, applications for the following specified categories of products shall be handled as set forth in paragraph (c) of this section:

(1) Therapeutic DNA plasmid products;

(2) Therapeutic synthetic peptide products of 40 or fewer amino acids;

(3) Monoclonal antibody products for in vivo use; and

(4) Therapeutic recombinant DNA-derived products.

(b) *Radioactive biological products.* In lieu of submitting an establishment and product license for the manufacture of a radioactive biological product, as defined in § 600.3(ee) of this chapter, the manufacturer of such a product shall submit a new drug application to the Director, Division of Medical Imaging, Surgical, and Dental Products (HFD–160), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, consistent with the procedures set forth in § 314.50 of this chapter. For such products, the approval of the new drug application will be in lieu of issuing a product and an establishment license. Compliance with the provisions of part 314 of this chapter shall be deemed to constitute compliance with the provisions of Subchapter F of this chapter unless the Commissioner makes a determination that a particular regulation from Subchapter F shall be applicable to radioactive drugs containing a biological product, e.g., § 610.2 of this chapter.

(c)(1) To obtain marketing approval for a therapeutic DNA plasmid product, therapeutic synthetic peptide product of 40 or fewer amino acids, monoclonal antibody product for in vivo use, or therapeutic recombinant DNA-derived product, an applicant shall submit to the Director, Center for Biologics Evaluation and Research, a biologics license application on a form prescribed by the Director, Center for Biologics Evaluation and Research. For such products, a separate establishment license application shall not be required. An application for a license for such a product shall include:

(i) Data derived from nonclinical laboratory and clinical studies that demonstrate that the manufactured product meets prescribed standards of safety, purity, and potency; with respect to each nonclinical laboratory study, either a statement that the study was conducted in compliance with the requirements set forth in part 58 of this chapter, or,

(ii) If the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance;

(iii) Statements regarding each clinical investigation involving human subjects contained in the application, that it either was conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter or was not subject to such requirements in accordance with §§56.104 or 56.105 of this chapter, and was conducted in compliance with requirements for informed consent set forth in part 50 of this chapter;

(iv) A full description of manufacturing methods;

(v) Data establishing stability of the product through the dating period;

(vi) Sample(s) representative of the product to be sold, bartered, or exchanged or offered, sent, carried or brought for sale, barter, or exchange;

(vii) Summaries of results of tests performed on the lot(s) represented by the submitted samples; and

(viii) Specimens of the labels, enclosures, and containers proposed to be used for the product.

(2) An application for license shall not be considered as filed until all pertinent information and data have been received from the applicant by the Center for Biologics Evaluation and Research. The applicant shall also include either a claim for categorical exclusion under §25.30 or 25.31 of this chapter or an environmental assessment under §25.40 of this chapter.

(3) Approval of the biologics license application and issuance of the biologics license shall constitute a determination that the establishment and the product meet applicable standards established in this chapter to ensure the continued safety, purity, and potency of such products. Applicable standards for the maintenance of establishments for the manufacture of a product subject to this paragraph (c) shall include the good manufacturing practice requirements set forth in parts 210 and 211 of this chapter. The following sections in parts 600 through 680 of this chapter shall not be applicable to such products: §§600.10(b) and (c), 600.11, 600.12, 600.13, 601.1, 610.11, 610.53, and 610.62 of this chapter.

(4) The term ''product license application,'' as it is used in those sections of parts 600 through 680 of this chapter that are applicable to products subject to this paragraph (c) shall include a biologics license application for a therapeutic DNA plasmid product, therapeutic synthetic peptide product of 40 or fewer amino acids, monoclonal antibody product for in vivo use, or therapeutic recombinant DNA-derived product.

(5) To the extent that the requirements in this paragraph (c) conflict with other requirements in this subchapter, this paragraph (c) shall supersede such other requirements.

(6) The applicant, or the applicant's attorney, agent, or other authorized official shall sign the application.

[40 FR 31313, July 25, 1975, as amended at 46 FR 8955, Jan. 27, 1981; 47 FR 6618, Feb. 16, 1982; 49 FR 23833, June 8, 1984; 50 FR 7518, Feb. 22, 1985; 50 FR 16669, Apr. 26, 1985; 55 FR 11013 and 11014, Mar. 26, 1990; 61 FR 24232, May 14, 1996; 62 FR 11769, Mar. 13, 1997; 62 FR 40600, July 29, 1997; 62 FR 53538, Oct. 15, 1997; 63 FR 5253, Feb. 2, 1998]

EFFECTIVE DATE NOTE: At 63 FR 5253, Feb. 2, 1998, §601.2 was amended in paragraph (a) by adding a sentence after the first sentence, effective Feb. 2, 1999.

§601.3 License forms.

(a) *Establishment license.* The establishment license form shall be prescribed by the Director, Center for Biologics Evaluation and Research and shall include:

(1) The name and address of the manufacturer.

(2) The name and address of the establishment.

(3) The names and addresses of all locations of the establishment.

(4) The license number.

(5) The date of issuance.

(b) *Product license.* The product license form shall be prescribed by the